K061615

# 510(k) Summary
# for
# Interdry Textile with Silver

DEC 2 2 2006

## 1. SPONSOR

Milliken Chemical
920 Milliken Rd.
PO Box 1927, M-209
Spartanburg, SC 29304

Contact Person: John D. Bruhnke, Ph.D.
Telephone: 864-503-2844

Date Prepared: June 8, 2006

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Interdry Textile with Silver |
| Common/Usual Name: | Skin Protectant |
| Classification Name: | Fiber, Medical, Absorbent |

## 3. PREDICATE DEVICE

- SurePress Absorbent Padding (21 CFR 880.5300)

## 4. DEVICE DESCRIPTION

Interdry Textile with Silver is a non-sterile skin protectant comprised of polyester knit textile substrate indicated for management of skin folds and other skin-to-skin contact areas and is offered as a 25.4 cm x 365.8 cm fabric piece, although other sizes may be available. The device provides moisture management to keep skin dry and the device's low coefficient of friction reduces skin-to-skin friction. Interdry Textile with Silver is a single patient use product that is custom cut from a multiuse package.

## 5. INTENDED USE

InterDry Textile with Silver is a skin protectant indicated for management of skin folds and other skin-to-skin contact areas. InterDry Textile with Silver reduces microbial colonization in the fabric.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Technological characteristics of Interdry Textile with Silver and the predicate product are substantially equivalent in that they are devices designed for moisture (fluid) absorption and are suitable for use on skin. The Interdry Textile with Silver is manufactured from a knitted polyester fabric containing a polyurethane coating (with AlphaSan RC-500) whereas the predicate, SurePress™ Absorbent padding, is a nonwoven fabric made from a blend of viscose/bicomponent with superabsorbent fibers (88:12). The only significant difference between the Interdry Textile with Silver and the predicate device is that Interdry Textile with Silver contains a small amount of a silver-based antimicrobial in a polyurethane coating for odor control. This additional function of Interdry Textile with Silver is minor and does not affect the safety or effectiveness of the device, as demonstrated by the biocompatibility and physical property tests that were performed and compared with the predicate device, SurePress™ Absorbent Padding.

## 7. PERFORMANCE TESTING

Biocompatibility testing was performed in accordance with the International Organization for Standardization recommendations. Results of the biocompatibility tests demonstrate that the device is suitable for its intended use. Antimicrobial testing was performed which showed that Interdry Textile with Silver provides an effective microbial barrier to the device itself. Milliken believes that the data included in this submission including the technical characteristics and physical properties demonstrate that Interdry Textile with Silver is substantially equivalent in design, function and intended use to the SurePress device. The additional antimicrobial feature of Interdry Textile with Silver does not affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2007

Milliken Chemical
C/O Mary McNamara-Cullinane
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K061615
Trade/Device Name: Interdry Textile with Silver
Regulation Number: 21 CFR 880.5300
Regulation Name: Medical Absorbent Fiber
Regulatory Class: I
Product Code: FRL
Dated: December 18, 2006
Received: December 19, 2006

Dear Ms. McNamara-Cullinane:

This letter corrects our substantially equivalent letter of December 22, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

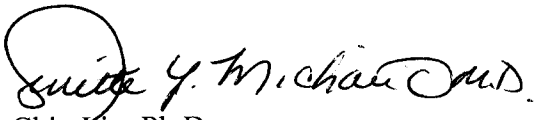
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K061615

Device Name: Interdry Textile with Silver

Indications for Use:

InterDry Textile with Silver is a skin protectant indicated for management of skin folds and other skin-to-skin contact areas. InterDry Textile with Silver reduces microbial colonization in the fabric.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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[illegible] Devices

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